

1 **Claims 1 – 15 (cancelled)**

1 **Claim 16. (new)** A classification and management system for patients with
2 lower extremity arterial occlusive disease comprising the steps of:

- 3 • examining a patient at a healthcare facility with lower extremity arterial
4 occlusion disease,
- 5 • collecting patient data including patient diagnoses, pertinent physical
6 findings and noninvasive arterial pressure and blood flow data,
- 7 • recording the collected patient data,
- 8 • transmitting said collected patient data to an evaluating authority,
- 9 • comparing said collected patient data against a medically accepted set
10 of disease specific criteria at the evaluating authority to provide an initial
11 diagnosis and preliminary classification of those patients “potentially at
12 risk” and those patients “not at risk” of developing complications of
13 arterial occlusive disease,
- 14 • transmitting said preliminary classification to the healthcare facility,
- 15 • referring those patients classified as “potentially at risk” of arterial
16 occlusive disease to an accredited laboratory for noninvasive vascular
17 evaluation,
- 18 • evaluating those “potentially at risk” patients at the accredited
19 laboratory against medically accepted criteria,
- 20 • recording the results of said noninvasive vascular evaluation at the
21 accredited laboratory,
- 22 • transmitting said recorded results to the evaluating authority for final
23 classification,
- 24 • classifying each patient at the evaluating authority against medically
25 accepted criteria as “at risk” or “not at risk”,
- 26 • transmitting said “at risk” or “not at risk” patient final classification to the
27 healthcare facility,
- 28 • recording said “at risk” or “not at risk” patient final classification at the
29 healthcare facility,
- 30 • referring patients having a final classification of “at risk” for critical
31 ischemia with associated extremity lesions and patients with
32 noninvasive evidence of severe ischemia to a vascular surgery facility

- 33 for vascular surgical assessment to determine whether
34 revascularization is necessary,
- 35 • assessing such “at risk” patients against medically accepted criteria as
36 “clinical indication for operation” or “no indication for operation” at the
37 vascular surgery facility,
 - 38 • transmitting patient assessments assessed as “clinical indication for
39 operation” or “no indication for operation” assessment to the evaluating
40 authority,
 - 41 • informing those patients assessed as “clinical indication for operation”,
 - 42 • electing either revascularization and periodic management system
43 evaluation at the healthcare facility or routine wound care and periodic
44 reevaluation at the healthcare facility by patients assessed as “clinical
45 indication for operation”,
 - 46 • monitoring patients assessed as “no indication for operation” by the
47 healthcare facility with increased precautions to monitor for detection of
48 any deterioration that would require reassessment,
 - 49 • referring patients having ulcers, pain or gangrene at the time of “no
50 indication for operation” assessment for reassessment,
 - 51 • recording the reasons for not referring such patients as “clinical
52 indication for operation”,
 - 53 • referring patients classified as “no indication for operation” that develop
54 ulcers, pair and/or gangrene to the vascular surgery facility for
55 reassessment,
 - 56 • reassessing the referred patient at the vascular surgery facility against
57 medically accepted criteria as “no indication for operation” or “clinical
58 indication for operation”,
 - 59 • transmitting the reassessment of “no indication for operation” or “clinical
60 indication for operation” to the evaluating authority for reevaluation as
61 “no indication for operation” or “clinical indication for operation”,
 - 62 • transmitting the reevaluation to the healthcare faculty with the
63 appropriate medical procedure and regimen,
 - 64 • treating and monitoring patients classified as “not at risk”, “at risk” and
65 assessed as “no indication for operation” or “clinical indication for
66 operation” at the healthcare facility,

- 67 • providing “not at risk” patients without limb ulcers routine care and
68 precautions at the healthcare facility,
- 69 • providing “not at risk” patients with limb ulcers routine wound care at the
70 healthcare facility,
- 71 • providing “not at risk” patients with limb ulcers periodic reevaluation by
72 the evaluating authority,
- 73 • providing “at risk” patients assessed as “no indication for operation” or
74 “operation not elected by patient”, and “clinical indication for operation”
75 patient undergoing revascularization at the vascular surgery facility with
76 intensive wound care at the healthcare facility, and,
- 77 • providing periodic reevaluations of “at risk” patients assessed as “no
78 indication for operation” or “operation not elected by patient” with
79 increased precautions at the healthcare facility.